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REMARKS/ARGUMENTS**Applicants' Invention**

By way of brief review, Applicant's invention is directed to an implantable tissue stimulation prosthesis that includes, *inter alia*, an "active electrode array". A key feature of Applicants' invention is that "the active electrode array provides a plurality of groups of electrodes, . . . any one of which may be selected to apply a stimulus pulse through active switching elements included within the array, preferably through the use of Stimulation Groups." Specification, page 3, lines 9-13.

The active switching elements which are included as part of the claimed "active electrode array" are included within the active electrode array, and are thus external to the hermetically sealed case. This allows a reduced number of feed-through terminals to be used in order to make needed electrical contact between the switching circuitry and electrodes of the active electrode array and the electronic circuitry within the hermetically sealed case.

Hence, it is important to recognize that the "active electrode array" claimed by Applicants is not like most electrode arrays of the prior art. Rather, Applicants' "active electrode array" includes active switching elements that allow switching to occur so that a stimulation signal, present on one of the wires within the electrode array, can be directed, or switched, by the switching circuitry included within the active electrode array, to an appropriate electrode contact. In contrast, most prior art electrode arrays are "passive", meaning that no switching function occurs within the electrode array; rather each electrode contact must have its own wire associated therewith, which must in turn be connected through its own feed through terminal to circuitry within the hermetically sealed case, all of which dramatically increases the number of wires that must be included within the electrode array and the complexity of the mechanical configuration of the feed through terminals.

Up until receipt of the most recent Office Action (mailed 8/29/2003), Applicants and their attorneys were not aware of any prior art that showed or suggested the use of an "active electrode array" of the type claimed by Applicants. However, in the most recent Office Action, the Schallhorn et al. reference (US Pat. 6,473,653) was cited by the Examiner, as new prior art (not cited in the first Office Action), for teaching an active electrode array. Applicants express appreciation to the Examiner for finding the Schallhorn et al. reference. While the type of active electrode array shown in the Schallhorn et al. reference is not the type of active electrode array contemplated by Applicants -- and is in fact quite different from Applicants' preferred active electrode array -- it is nonetheless an active electrode array that requires a narrowing of some

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of Applicants' claims. Hence, the amended claims submitted herewith have been amended in order to clearly distinguish Applicants invention over Schallhorn et al.

Claim Rejections under 35 U.S.C. §103

In order to facilitate a comparison of the response presented below with the rejections made by the Examiner in the Office action mailed 8/29/2004, the paragraph numbers used below correspond, insofar as possible, with the paragraph numbers used by the Examiner in the Office action mailed 8/29/2003.

1. The Examiner quoted 35 U.S. C. §103(a) which forms the basis for all of the obviousness rejections set forth in the Office action.
2. The Examiner rejected Claim 1 under 35 U.S.C. §103(a) as being unpatentable (obvious) over Loeb et al. (5,649,970) in view of Schallhorn et al (6,473,653) and further in view of Muller (5,814,095).

Before substantively addressing this rejection, Applicants would like to correct an error (which is believed to be inadvertent) which propagated through the Office action. The Examiner characterized Loeb et al. as showing, *inter alia*, "an active electrode array external to the hermetically sealed case (FIGS. 5-7)". It is respectfully pointed out that this characterization of Loeb et al. is in error. Applicants' attorney, whose signature appears below, prepared and prosecuted the Loeb et al. reference, and knows first hand that Loeb et al. most certainly does not show an active electrode array. Rather, Loeb et al shows only a passive electrode array. The term "active", as used in the instant application (and as generally understood in the art) requires some type of switching circuitry built into the electrode array (external to the hermetically sealed case). Even the Examiner acknowledges that "Loeb et al. fails to show the electrode array comprises switching circuitry that is external to the hermetically sealed case", (Office Action mailed 8/29/03, page 2, lines 4-5 from bottom of page). Therefore, the Examiner clearly understands this deficiency in the teachings of Loeb et al., but nonetheless continued throughout the Office Action to incorrectly characterize Loeb et al. as showing an "active electrode array". Applicant believes that this mischaracterization of Loeb et al. (calling a passive electrode array an active electrode array) is a harmless error because the Examiner did correctly articulate what Loeb et al. fail to teach (switching circuitry built into the electrode array, or external to the hermetically sealed case). Applicants point out this error only for the purpose

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of making sure the record clearly shows that Applicants do not agree nor concede that Loeb et al. teach an active electrode array.

After making the incorrect characterization of the Loeb et al. reference, the Examiner combined the teachings of Schallhorn et al with Loeb et al. and concluded that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the tissue stimulation prosthesis of Loeb et al with the electrode array switching circuitry of Schallhorn et al. The Examiner then combined the teachings of Muller with those of Loeb et al. and Schallhorn et al to conclude that it would have also been obvious to one of ordinary skill in the art at the time the invention was made to modify the Loeb et al. and Schallhorn et al. device with the implantable microphone and battery of Muller. Based on the teachings of these combined references, the Examiner thus rejected Claim 1 as unpatentable under 35 U.S. C. §103(a).

The above rejection of Claim 1 is overcome by way of the present amendment because Claim 1 has been amended to incorporate therein the subject matter of objected-to Claim 5, and includes the limitations of the base claim and the intervening claims. That is, the amendment made herewith to Claim 1 is the equivalent of rewriting original Claim 5 in independent form so as to include all the limitations of the base claim and any intervening claims. With such amendment, Claims 2-5 have been canceled because the subject matter of all those claims has been incorporated into currently amended Claim 1, and Claim 6 has been amended to make it dependent upon currently amended Claim 1, rather than canceled Claim 5.

3. The Examiner rejected Claims 2-4 and 8-10 under 35 U.S. C. §103(a) as being unpatentable over Loeb et al (5,649,970) in view of Schallhorn et al (6,473,653) and Muller (5,814,095) as applied to Claim 1 and further in view of Kuzma (5,105,811). By way of the present amendment, Claims 2-4 have been canceled, so this rejection is moot relative to Claims 2-4. For Claims 8-10, this rejection is overcome by way of the present amendment for the same reasons given above in support of currently amended Claim 1, upon which Claims 8-10 depend.

4. The Examiner rejected Claims 11-12 under 35 U.S. C. §103(a) as being unpatentable over Loeb et al (5,649,970) in view of Schallhorn et al (6,473,653) and Muller (5,814,095) as applied to Claim 1 and further in view of Soykan et al (6,236,889). This rejection is overcome by way of the present amendment for the same reasons given above in support of currently amended Claim 1, upon which Claims 11-12 depend.

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5. The Examiner rejected Claim 13 under 35 U.S. C. §103(a) as being unpatentable over Loeb et al (5,649,970) in view of Schallhorn et al (6,473,653) and Muller (5,814,095) and Soykan et al (6,236,889) as applied to Claim 12 because the subject matter of Claim 12 would, in the Examiner's view, be an obvious design choice. While not agreeing with this view (and in fact, strongly disagreeing with this view¹), this rejection is overcome by way of the present amendment for the same reasons given above in support of currently amended Claim 1, upon which Claim 13 depends.

6. The Examiner rejected Claims 1, 7 and 14-15 under 35 U.S. C. §103(a) as being unpatentable (obvious) over Faltys et al. (6,289,247) in view of Schallhorn et al (6,473,653) and further in view of Muller (5,814,095). This rejection is overcome by way of the present amendment for the same reasons given above in support of currently amended Claim 1, upon which Claims 11-12 depend.

7. The Examiner rejected Claims 2-4 and 8-10 under 35 U.S. C. §103(a) as being unpatentable over Faltys et al. (6,289,247) in view of Schallhorn et al (6,473,653) and Muller (5,814,095) as applied to Claim 1 and further in view of Kuzma (5,105,811). By way of the present amendment, Claims 2-4 have been canceled, so this rejection is moot relative to Claims 2-4. For Claims 8-10, this rejection is overcome by way of the present amendment for the same reasons given above in support of currently amended Claim 1, upon which Claims 8-10 depend.

8. The Examiner rejected Claims 11-12 under 35 U.S. C. §103(a) as being unpatentable over Faltys et al. (6,289,247) in view of Schallhorn et al (6,473,653) and Muller (5,814,095) as applied to Claim 1 and further in view of Soykan et al (6,236,889). This rejection is overcome by way of the present amendment for the same reasons given above in support of currently amended Claim 1, upon which Claims 11-12 depend.

¹It is improper for the Examiner to shift the burden of patentability upon the Applicant to show criticality and/or unexpected results. There is nothing in the patent statute that requires an Applicant to disclose that certain claimed features are critical or that the use of such features produces unexpected results. All the Applicant is required to disclose is what his or her invention is, with enough specificity to enable a person skilled in the art to practice the invention, along with what the best mode of the invention is. Should the Examiner believe a claimed feature is a mere "design choice", that is simply another way of stating that the Examiner believes the invention is obvious, and in such case the burden is on the Examiner to come forward with prior art supporting such obviousness conclusion. He or she cannot properly support such obviousness conclusion with a negative -- assuming it is obvious because of what the Applicant chose not to disclose.

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9. The Examiner rejected Claim 13 under 35 U.S. C. §103(a) as being unpatentable over Faltys et al. (6,289,247) in view of Schallhorn et al (6,473,653), Muller (5,814,095) and Soykan et al (6,236,889) as applied to Claim 12 above. While not agreeing with this view (and in fact, strongly disagreeing with this view as previously pointed out in footnote 1), this rejection is overcome by way of the present amendment for the same reasons given above in support of currently amended Claim 1, upon which Claim 13 depends.

10. The Examiner correctly pointed out that the Faltys et al. reference has a common inventor with the instant application, and that as such it only qualifies as prior art under 35 U.S.C. §102(e), and further that the rejections which relied on Faltys et al. could thus be overcome by removing the 102(e) art through proper showings (i.e., not the invention of "another"; establishing an earlier date of invention; or establishing commonly owned reference and application coupled with a terminal disclaimer). Applicant appreciates the Examiner pointing out these possibilities for overcoming the Faltys-based rejections. However, in this instance, the Faltys-based rejections have already been overcome for the same reasons given above in support of currently amended Claim 1.

11. The Examiner rejected Claims 16-18 under 35 U.S. C. §103(a) as being unpatentable over Loeb et al (5,649,970) in view of Schallhorn et al (6,473,653). By way of the present amendment, Claim 16 has been amended to incorporate therein the subject matter of objected-to Claim 19, and includes the limitations of the base claim and the intervening claims. That is, the amendment made herewith to Claim 16 is the equivalent of rewriting original Claim 19 in independent form so as to include all the limitations of the base claim and any intervening claims. With such amendment, Claims 17-19 have been canceled because the subject matter of all those claims has been incorporated into currently amended Claim 16, and Claim 20 has been amended to make it dependent upon currently amended Claim 16; rather than canceled Claim 19. Hence, currently amended Claim 16, and all the claims that depend therefrom, should now be allowable.

12. The Examiner withdrew the previously-indicated allowability of Claims 27-32, and rejected Claims 27, 28, 29 and 30 under 35 U.S. C. §103(a) as being unpatentable over Loeb et al (5,649,970) in view of Schallhorn et al (6,473,653), Muller (5,814,095) and Kuzma (5,105,811). By way of the present amendment, it is submitted that this rejection has been overcome because the same subject matter of objected to Claim 19 --which claims the specific structure of Applicants' active electrode array, including active switching elements which

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comprise decoding circuitry, a first switch coupled to the decoding circuitry and at least one lateral electrode contacts, and a second switch coupled to the decoding circuitry and at least one medial electrode contact, which subject matter is not shown nor suggested in Schallhorn et al nor any other known prior art – has been amended into currently amended Claim 27. Hence, it is respectfully submitted that currently amended Claim 27 distinguishes over Loeb et al (5,649,970) in view of Schallhorn et al (6,473,653), Muller (5,814,095) and Soykan et al (6,236,889), and is allowable, as are Claims 28-30, which depend from currently amended Claim 27.

13. The Examiner also rejected Claims 31-32 under 35 U.S. C. §103(a) as being unpatentable over Loeb et al (5,649,970) in view of Schallhorn et al (6,473,653), Muller (5,814,095) and Kuzma (5,105,811) as applied to Claim 27, and further in view of Soykan et al (6,236,889). Claims 31 and 32 depend from currently amended Claim 27. Hence, this rejection is overcome for the same reasons given above in support of currently amended Claim 27.

14. New claims 33-37 are presented herewith. Claim 33 is an independent claim patterned after the subject matter of original Claims 1 and 5. Inasmuch as original Claim 5 included allowable subject matter, it is respectfully submitted that new Claim 33 should also be allowable, i.e., the prior art does not show or suggest a fully implantable tissue stimulation prosthesis that includes, *inter alia*, an active electrode array external to an hermetically sealed case, comprising at least a plurality of medial electrode contacts, a plurality of lateral electrode contacts, and switching circuitry, and wherein at least one of the plurality of medial electrode contacts or at least one of the plurality of lateral electrode contacts may be individually activated by electrode control signals applied to the switching circuitry, and wherein the switching circuitry and lateral and medial electrode contacts are formed on a silicon die, and wherein a plurality of the silicon dies are stacked and over-molded with silastic to form the active electrode array. Claim 34 depends from Claim 33 and should be allowable for at least the same reason that Claim 33 should be allowable.

Claim 35 is an independent claim patterned after the subject matter of original Claims 16 and 19. Inasmuch as original Claim 19 included allowable subject matter, it is respectfully submitted that new Claim 35 should also be allowable, i.e., the prior art does not show an implantable tissue stimulation prosthesis that includes, *inter alia*, an active electrode array external to an hermetically sealed case comprising a plurality of active electrodes, wherein each active electrode includes first and second electrode contacts, decoding circuitry, a first switch

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coupled to the decoding circuitry and the first electrode contact, and a second switch coupled to the decoding circuitry and the second electrode contact, and wherein the decoding circuitry responds to electrode control signals and causes the first and second switches to selectively activate one or both of the first or second electrode contacts. Claims 36 and 37 depend from Claim 35 and should be allowable for at least the same reasons that Claim 35 should be allowable.

In view of the foregoing remarks and amendments, it is respectfully submitted that the rejections have been overcome and that the previously-rejected pending claims and the newly submitted claims are in condition for allowance. An early indication of allowability of Claims 1, 6-16 and 20-37 is earnestly solicited.

Respectfully Submitted,



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